

## **REMARKS**

### **STATUS OF THE CLAIMS**

Claims 1, 5-11, 14-16, 19, 22-24, 31, 32 and 34-37 were pending. Claims 2-4, 12, 13, 17, 18, 20, 21 and 25-30 have been canceled. Claims 5, 6, 22, 31, 32, 34, 35, 36, and 37 have been withdrawn from consideration. Claims 1, 7-11, 14-16, 19, 23 and 24 were examined. By amendment herein, duplicative recitations in claim 1 have been removed. As this amendment does not raise any issues of new matter or necessitate additional searches, it simplifies the issues for appeal and, accordingly, should be entered after final. Thus, claims 1, 5-11, 14-16, 19, 22-24, 31, 32 and 34-37

### **CLAIM OBJECTIONS**

The objection to the repeated phrase in claim 1 has been obviated by the foregoing amendment.

### **35 U.S.C. § 102(b)**

Claims 1, 7, 11, 19 and 24 were again rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,658,308 (hereinafter "Snyder"). (Office Action, page 2). Snyder was cited for allegedly disclosing "a vaso-occlusive coil for treating aneurysms having a thrombogenic/fibrinogenic bioactive coating (see, figures 1-3 and claims 2 and 3)." *Id.* In response to Applicants' previous arguments that Snyder does not disclose a vaso-occlusive composition consisting of the recited bioactive materials (fibrin; polyethylene glycol derivatives; thrombin-coated gelatin granules; balloons coated with iron microspheres; trace metals; and thrombus-stabilizing molecules), the Examiner stated, in part (page 5 of Final Office Action):

As is well known in the art, fibrin is a protein involved in the clotting of blood. It is a fibrillar protein that is polymerised to form a "mesh" that forms a hemostatic plug or clot (in conjunction with platelets) over a wound site. Fibrin is made from is zymogen fibrinogen, a soluble plasma glycoprotein that is synthesized by the liver and fibrinogen is a principal protein of blood clotting. Snyder discloses thrombus-stabilizing molecules, fibrin or combinations thereof as disclosed in claim 1 (see claims 2 and 3 of Snyder).

Anticipation is a rigorous standard – every limitation of the claim at issue must appear identically in a single reference for a rejection under 35 U.S.C. § 102 to stand. *In re Bond*, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Therefore, in the instant case, Snyder must identically disclose a vaso-occlusive device consisting of a vaso-occlusive member and a bioactive material selected from the group consisting of fibrin; polyethylene glycol derivatives; thrombin-coated gelatin granules; balloons coated with iron microspheres; trace metals; thrombus-stabilizing molecules; and combinations thereof.

In point of fact, Snyder is silent as to “fibrin” and only discloses vaso-occlusive devices which include polymeric strands extending through their lumens. As recited in claims 2 and 3 of Snyder, these polymeric strands may be “fibrogenic,” but they do not consist of fibrin (or any of the other bioactive materials), as set forth in the pending claims. The Examiner has not shown that Snyder’s polymeric strands are thrombogenic and/or fibrogenic by virtue of any one of the recited bioactive materials and, indeed, none of the recited materials appear in Snyder’s disclosure.

Given Snyder’s clear failure to disclose devices consisting of fibrin *per se*, the basis of the rejection seems to be that Snyder’s polymeric strands can be “fibrogenic” by recruiting endogenous fibrin and that this somehow means that the endogenous fibrin is part of the Snyder’s device. As noted above, the Examiner attempts to support this argument by reiterating well known characteristics of endogenous fibrin.

However, the nature of endogenous fibrin, and whether this endogenous fibrin is recruited by Snyder’s devices, is irrelevant to the particularly claimed compositions. The Examiner has not established that Snyder’s devices necessarily recruit endogenous fibrin. Even if this could be established, Snyder still cannot anticipate any of the claimed devices, which consist of the recited molecules, including isolated fibrin.

Simply put, Snyder’s disclosure of thrombogenic/fibrogenic polymeric strands extending through the lumen of a vaso-occlusive coil does not anticipate, explicitly or implicitly, the subject matter of claims 1, 7, 11, 19 or 24 and, accordingly, withdrawal of the rejection is in order.

**35 U.S.C. § 103**

**A. Claims 8, 9, 10 and 23**

Claims 8, 9, 10 and 23 were again rejected under 35 U.S.C. § 103(a) as allegedly obvious over Snyder in view of U.S. Patent No. 4,414,976 (hereinafter "Schwarz"). (Office Action, page 3). Snyder was cited for disclosing "thrombogenic" devices and Schwarz was cited for allegedly teaching a tissue adhesive made with Factor XIII, plasminogen activator inhibitor or plasmin inhibitor. *Id.*

Obviousness is only established when the subject matter of a claim as a whole would have been obvious to the skilled artisan. For the reasons detailed above, Snyder does not disclose or suggest vaso-occlusive composition consisting of the particular thrombus-stabilizing materials recited in claims 8, 9, 10 and 23. Disclosing that polymeric fibers are "thrombogenic" is **not** the same as disclosing a device consisting of the recited thrombus-stabilizing molecule or the other recited bioactive materials of the claims and would not be so viewed by the skilled artisan. Common knowledge regarding the biology and function of endogenous fibrin (or endogenous thrombus-stabilizing molecules) is irrelevant to the compositions of claims 8, 9, 10 and 23, which consist of isolated recited thrombus-stabilizing molecules not disclosed or suggested in Schwarz.

For its part, Schwarz is completely silent as to coils or vessel occlusion, disclosing instead a tissue adhesive comprising fibrinogen and Factor XIII to "seamlessly connecting tissue or organ parts, for sealing wounds, stopping bleeding and stimulating wound healing in mammals." *See*, claim 1 of Schwarz.

Thus, withdrawal of the rejection is in order.

**B. Claim 14**

Claim 14 was again rejected as allegedly obvious over Snyder in view of U.S. Patent No. 6,231,590 (hereinafter "Slaikeu"). (Office Action, page 3). Snyder was cited as disclosing the "claimed invention except for the member being plasma-treated" and Slaikeu was cited for teaching plasma treated devices. (Office Action, page 6).

For the reasons listed above, Snyder in no way discloses or suggests the claimed subject matter. Indeed, Snyder's polymeric strands are not made of fibrin or any other bioactive material

claimed by Applicants. Accordingly, the skilled artisan would not (and indeed could not) have been motivated from Snyder, alone or in combination with Slaikeu to arrive at the invention of claim 14.

**B. Claim 15**

Claim 15 was again rejected as allegedly obvious over Snyder in view of U.S. Patent No. 5,891,192 (hereinafter "Murayama"). (Office Action, page 3). Snyder was cited as above with regard to claim 14 and Slaikeu was cited for teaching ion implantation. *Id.*

Since Snyder does not teach or suggest the particularly claimed bioactive materials, the skilled artisan would not (and indeed could not) have been motivated from Snyder in any combination with Murayama, to arrive at the invention of claim 15. Accordingly, withdrawal of the rejection is in order.

**C. Claim 16**

Claim 16 was again rejected as allegedly obvious over Snyder in view of U.S. Patent No. 6,526,979 (hereinafter "Nikolchev"). (Office Action, page 4). Snyder was cited as above and Nikolchev was cited for teaching microtexturing. *Id.*

For the reasons listed above with respect to the rejections of claims 14 and 15, Snyder does not teach or suggest the compositions of claim 16 and, therefore, there is no motivation to combine these references and no combination of Snyder and Nikolchev that would result in the claimed compositions. Thus, the rejection is untenable.


**CONCLUSION**

For the reasons discussed above, Applicants submit that the claims are in condition for allowance and request early notification to that effect.

If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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